UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA& UPJOHN COMPANY, G.D. SEARLE & CO, G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA) Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIV. ACTION NO. 04-754 (JCL) **OPINION** Teva's In Limine Motion No. 1

LIFLAND, District Judge

This case arises out of Teva Pharmaceuticals U.S.A., Inc.'s ("Teva" or "Defendant") alleged infringement of U.S. Patent Nos. 5,466,823; 5,563,165; and 5,760,068 (the "patents-in-suit"), which are held by Pfizer, Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively "Pfizer" or "Plaintiffs"). The patents-in-suit are directed toward celecoxib, the active ingredient in Celebrex, and a broad genus of compounds that includes celecoxib, pharmaceutical compositions including such compounds, and methods

of using such compounds.

Before the Court is Teva's in limine motion No. 1, which contains three separate but related arguments. The Court rendered a decision on Teva's first argument in an Opinion and Order dated October 13, 2006. This Opinion deals exclusively with Teva's second and third arguments, both of which involve Pfizer's intention to submit evidence aimed at disqualifying the Merck U.S. patent No. 5,474,995 (the "Merck '995 patent") as a prior art reference.

Since fairly early in this litigation, Teva has indicated that it plans to rely on the Merck '995 patent as a prior art reference to demonstrate the obviousness of the patents-in-suit. Based on the general information the parties have provided to the Court thus far, Teva's theory of obviousness (in somewhat simplified terms) seems to be that a hypothetical person with ordinary skill in the relevant art could construct a hypothetical pharmacophore based on the Merck '995 patent and the Fujisawa European application No. 055, 829 (the "Fujisawa '829 application"), and then use the Fujisawa '829 application to select twelve compounds embraced by the pharmacophore, including celecoxib.

In a September 8, 2006 draft of the Pre-Trial Order ("PTO"), Pfizer indicated for the first time that it planned to argue that the Merck '995 patent should not be considered prior art. In the next draft of the PTO, dated September

15, 2006, Pfizer expanded on this idea. Pfizer wrote:

> 1. Pfizer conceived of and synthesized numerous diphenyl heterocycle compounds, including compounds containing either a para-methylsulfonyl [or] para-sulfamyl on a phynel ring prior to June 24, 1993, and worked with reasonable diligence continuously until filing for patent protection; and
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> 2. The Merck '995 patent is not entitled to the June 24, 1993 filing date of the Merck '196 application because the applicant added substantial new matter required to support the claims that issued in the '995 patent.

(Declaration of Michael E. Patunas in Support of Teva's Motion in Limine No. 1 (hereinafter, "Petunas Decl."), Ex. G.)

Teva sent a letter to Pfizer seeking more information on these positions. In its September 28, 2006 response to Teva's request, Pfizer indicated that the Merck '995 patent should be disqualified because Pfizer "was in prior possession of compounds sufficient (under Teva's reasoning) to put it in possession of the alleged pharmacophore" prior to the earliest possible filing date for the Merck '995 patent. With respect to its second argument, Pfizer declared its intent to argue that the Merck '995 patent is not entitled to the June 24, 1993 filing date of the Merck application serial number 08/082,186 (the "Merck '196 application") because the Merck '196 application does not enable the claims of the Merck '995 patent and/or does not provide adequate written description support for those

claims under 35 U.S.C. § 112. (See Id., Ex. C.)

In the instant motion, Teva argues that Pfizer should be precluded from offering evidence in support of these arguments.

I.

Pfizer's first argument—as articulated in the September 15 draft of the PTO and the September 28 letter to Teva—was essentially as follows. The earliest possible filing date for the Merck '995 patent is June 24, 1993.[1] By that date, Pfizer had already invented compounds "sufficient to teach" the hypothetical pharmacophone, which Teva asserts was obvious based on the Merck '995 patent. The Merck '995 patent, Pfizer concluded, should therefore be disqualified as a prior art reference.

In its opposition papers to the instant motion, however, Pfizer appears to have altered its position. Pfizer now argues that both the Merck '995 patent and the Fujisawa '829 application should be disqualified as prior art references. Specifically, Pfizer now claims that by June 24, 1993, Pfizer "had recognized at least as much about potentially GI-sparing [Non Steroidal Anti-Inflammatory Drugs] as was disclosed by the combination of the '995 patent and the '829

[1] Pfizer contests that the Merck '995 patent is entitled to this filing date. See infra Part II.

application," and had invented numerous compounds that—under Teva's obviousness reasoning—would render the patents-in-suit obvious. (Pfizer's Opposition to Teva's in Limine Motion No. 1, at 8 (emphasis added).)

Teva argues that the Court should preclude Pfizer from offering evidence regarding prior possession of sufficient information to disqualify the Merck '995 patent (the "prior possession argument") because: (1) Pfizer's late disclosure of its prior possession argument will cause Teva to suffer "great prejudice" ; (2) the evidence in support of the argument is irrelevant; and (3) the evidence is insufficient to demonstrate that Pfizer was, in fact, in prior possession of the teachings of the Merck '995 patent.[2] The Court will address each of these arguments in turn.

A. Prejudice

Teva contends that because Pfizer failed to disclose its prior possession argument until after the close of discovery, Teva will be greatly prejudiced if Pfizer is permitted to pursue the argument at trial. (Memorandum in Support of

[2] Because Pfizer's amended prior possession argument was set forth for the first time in its memorandum in opposition to the instant motion, Teva geared its argument toward the prior possession argument that was previously articulated by Pfizer. To the extent that the change in Pfizer's theory affects the issues before the Court, the Court will address both the previous and current incarnation of Pfizer's prior possession argument.

Teva's in Limine Motion No. 1, at 6 ("Due to the disclosure of th[is] argument[] after the close of expert discovery, Teva had no opportunity to do discovery of its own on these issues.").) To prevent such prejudice, Teva argues, the Court should preclude Pfizer from offering evidence in support of the argument under Federal Rule of Civil Procedure 37(c) and Federal Rule of Evidence 403. In the alternative, Teva asks the Court to permit it to submit additional expert reports addressing the issue. The Court does not find either form of relief to be warranted.

As an initial matter, Rule 37 is not implicated by the facts presented here. Rule 37 provides:

> A party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1), or to amend a prior response to discovery as required by Rule 26(e)(2), is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed.

Fed. R. Civ. P. 37. Thus, Rule 37 provides a remedy for failure to disclose information that is required by Rule 26(a) or 26(e)(1). Pfizer was not obliged to disclose its prior possession argument under either of these discovery rules. Such legal theories are not within the realm of the required disclosures under Rule 26(a). Nor has Teva identified any interrogatory or other discovery request that called for such information. Indeed, Teva does not direct the Court to any authority which required Pfizer to make a pre-litigation disclosure of all its legal

theories. In short, Pfizer had no obligation to *sua sponte* disclose its legal theories to Teva.

Morever, as Teva concedes, the facts underlying Pfizer's argument were all disclosed during the course of discovery. Teva admits that it failed to appreciate the significance of these facts or investigate them further, but that does not warrant either preclusion of the argument or an extension of Teva's time to conduct such an investigation.

B. Relevance

Teva next argues that evidence in support of Pfizer's prior possession argument is irrelevant because Pfizer has not alleged that it conceived of the inventions at issue any earlier than August 2, 1993, and in order "to remove the Merck '995 patent as Section 102(e) prior art, Plaintiffs must prove conception of the claimed invention—not conception of [its] teachings . . . —prior to June 24, 1993." (Memorandum in Support of Teva's in Limine Motion No.1, at 9.) Teva misstates the applicable law.

An applicant for a patent or a patent holder may disqualify a prior art reference cited as showing obviousness under § 103 by establishing "completion of the invention in this country" prior to the effective date of the reference. See 37

C.F.R. § 131.1.[3] This requirement is clearly met by showing prior completion of the entire invention as it is later claimed. However, it can also be met by showing prior possession of as much of the invention as is disclosed in the reference, see In re Stempel, 241 F.2d 755 (CCPA 1957), or prior "possession of such as to make the entire invention or that part obvious to one with ordinary skill in the art," see 3 Chisum on Patents § 3.08[1][b][ii], at 238. Thus, Teva's statement of the law—i.e. that Pfizer must show conception of the entire claimed invention prior to the reference date—is incorrect.

Moreover, evidence in support of Pfizer's current articulation of its prior possession argumen is in fact relevant. Evidence showing Pfizer had prior possession of compounds that encompassed the teachings of the Merck '995 patent and the Fujisawa '829 application and rendered the patents-in-suit obvious (under Teva's obviousness theory) could establish prior "possession of such as to make the entire invention . . . obvious to one with ordinary skill in the art." Such a showing could disqualify both the Merck '995 patent and the Fujisawa '829 application as prior art references.

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[3] Completion is defined as "either (1) reduction to practice prior to the effective date of the reference or (2) conception of the invention prior to the effective date of the reference. Coupled with due diligence from said date to subsequent reduction to practice or to the filing of the application." 3 Chisum on Patents § 3.08[1], at 226-27 (internal quotation marks omitted).

The relevance of evidence in support of the previous incarnation of Pfizer's prior possession argument is less clear; however, the Court finds that such evidence would be relevant as well. As explained above, a patent holder may satisfy its burden of establishing "completion of the invention in this country" by showing prior possession of as much of the invention as is disclosed in the disputed reference. See In re Stempel, 241 F.2d 755 (CCPA 1957). Admittedly, Pfizer did not claim prior possession of the compounds disclosed in the Merck '995 patent. However, Pfizer did claim that it had prior possession of the "teachings" of the disputed reference—i.e. the hypothetical pharmacophore that Teva contends was an obvious outgrowth of the Merck '995 patent. Although the relevant caselaw does not specifically deal with this situation, the Court finds that such a showing would satisfy the "completion of the invention in this country" requirement.

In In re Stempel, the Court of Customs and Patent Appeals explained that "all [an] applicant can be required to show is priority with respect to so much of the claimed invention as the reference happens to show." Id. at 759. It would be illogical to hold that an applicant cannot meet this burden by showing more of the claimed invention than the reference happens to show, especially where, as here, the "something more" is alleged by the defendant to be a crucial link between the

reference and the claimed invention. Accordingly, the Court finds that the disputed evidence is relevant under either incarnation of Pfizer's prior possession argument.

C. Sufficiency of the Evidence

Teva's final argument with respect to Pfizer's prior possession argument is that the evidence Pfizer offers in support of the argument is insufficient to demonstrate that Pfizer was, in fact, in prior possession of the teachings of the Merck '995 patent. This is not a proper basis for preclusion. If, after hearing the evidence, the Court determines that the evidence is in fact insufficient, the Court will rule against Pfizer on this issue. The Court will not, however, preclude the evidence on this ground.

Accordingly, Teva's motion to preclude Pfizer from offering evidence intended to show prior possession of the teachings of the Merck '995 patent will be denied.

II.

Turning to Pfizer's second argument, and Teva's objection thereto, it is first necessary to review some relevant dates. On June 24, 1993, Merck filed the Merck '196 application. Although this application was ultimately abandoned, portions of it were copied into the Merck '995 patent, which issued on December

12, 1995, from another application (08/179,467) filed on November 30, 1993. Since the Merck '995 patent was filed and issued after the filing date of the patents-in-suit, it cannot on its own be considered prior art. Similarly, the abandoned Merck '196 application cannot be considered prior art. See In re Wertheim, 646 F.2d 527, 535 (Fed. Cir. 1981) (explaining that "an abandoned application by itself can never be a reference"). However, Teva argues that the portions of the Merck '995 patent that were disclosed in the Merck '196 application are entitled to the June 24, 1993 filing date, and therefore qualify as prior art. Pfizer disagrees.

As explained above, Pfizer indicated in September 2006 that it intends to argue that the Merck '995 patent is not entitled to the earlier filing date from the Merck '196 application. Specifically, Pfizer claims that "only if the disclosure in the abandoned '196 application satisfies section 112 for the claims that issued in the '995 patent can the '995 patent properly claim June 24, 1993 as its § 102(e) date." (Pfizer's Opposition to Teva's in Limine Motion No.1, at 11-12.) Teva argues that Pfizer should not be permitted to introduce evidence in support of this argument because Pfizer failed to disclose this position until after the close of expert discovery, thus denying Teva the opportunity to conduct discovery on the issue. The Court disagrees.

As explained above, Pfizer was not required to *sua sponte* disclose its legal theories to Teva prior to preparing the proposed Pretrial Order. Essentially for the reasons laid out in Part I.A of this opinion, Teva's motion to preclude Pfizer from offering evidence intended to show that the Merck '995 is not entitled to the June 24, 1993 filing date will be denied.

/s/ John C. Lifland, U.S.D.J.

Dated: October 25, 2006